

REMARKS

Claims 8-28 and 30-54 are pending in this application. Of these claims, claims 8, 31 and 43 are independent claims.

Throughout the claims in this amendment, "blood component collection soft goods" has been replaced by "blood component collection kits". As previously recited in Claims 10, 24, 33 and 45, the blood component collection soft goods were selected from a group consisting of blood component collection kits, a blood component collection solution, and blood component collection transfer pack.

In the final Office Action, mailed January 6, 2009, claims 8-54 were rejected as obvious under 35 U.S.C. §103(a) over FLETCHER-HAYNES et al. (2001/0034614), previously cited, in view of the newly cited and relied upon WOJCIK et al. (5,666,493).

The present invention is directed to a system (Claims 8-30), a computer readable medium (Claims 31-42) and a method (Claims 43-54) for managing an inventory of blood component collection kits to prevent the use of those kits which have been quarantined before they are used. Blood component collection kits typically come in a sealed package and provide the equipment for the collection of the blood or blood components from the donor, such as tubing, needles, containers and solutions needed for that purpose. See paragraphs 0392-3. Some of such kit packages may become quarantined before they are

used (paragraphs 0105, 0268 and 0392-3) for any one of a number of possible reasons, such as previously opened or not sterile, becoming damaged or kinked, having passed the applicable use date or having been superseded by upgraded kits.

FLETCHER-HAYNES discloses a computerized blood collection system which is designed to optimize and maximize the yield of desired blood components, such as platelets, plasma and red blood cells. See the Abstract and paragraphs 0162 and 0195. Disposable tubing such as may be utilized during the blood collection may also be identified and recorded (paragraph 0083), tubing size type and bag identifiers may be recorded (paragraph 0125) presumably to be able to determine which tubing was used with a given donor, and the type of tubing may be placed in a final report (paragraph 0166). However, there is no disclosure or suggestion whatsoever in FLETCHER-HAYNES of inventorying any of the blood component collection kits or of quarantining such blood component collection kits either before or after use in the collection of blood from the donor. FLETCHER-HAYNES is absolutely silent in these aspects.

Indeed, such failure of disclosure or suggestion in FLETCHER-HAYNES is admitted in the last Office Action, page 3, where it is stated:

Fletcher, however fails to expressly disclose a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine

information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component soft good; and

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component soft good.

Having admitted these critical failures of disclosure or teaching of FLETCHER-HAYNES, it is then stated in the Office Action at the top of page 4 that:

Nevertheless, these features are old and well known in the art, as evidenced by Wojcik.

In an attempt to justify this application of the newly cited WOJCIK to supplement the critical deficiencies of FLETCHER-HAYNES, this statement is followed on page 4 of the Office Action by the following statement:

In particular, Wojcik discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component soft good (Wojcik: col. 16, 53-60); and

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component soft good (Wojcik: col. 16, 53-60).

Quite to the contrary, WOJCIK does not even relate to (1) any blood processing procedures, (2) a system for collecting a blood component, (3) a

system for preventing the use of quarantined blood component collection kits, (4) a system computer which has blood component collection kit quarantine information in a database, (5) a system computer which processes the quarantine information in the database prior to use of a blood component collection kit, and/or (6) an interface having a quarantine field for indicating that at least a portion of the blood component collection kit inventory is quarantined; all as claimed herein.

Instead, WOJCIK is directed to a system for receiving and managing customer orders, particularly with respect to food processing and distribution. According to WOJCIK at col. 1, lines 7-13, their invention is directed to:

[A] system for providing efficient management and fulfillment of customer orders in a food processing and distribution environment. More specifically, the invention relates to a system having an order management function, integrated with financial services to process orders promptly and create current and efficient financial records.

Thus, contrary to the statements at p.4 of the Office Action, Wojcik does NOT disclose (1) a system for managing inventory of blood component collection kits and for preventing the use of quarantined blood component collection kits, NOR does Wojcik disclose a system database having a blood component collection kit inventory and quarantine information prior to use of the blood component collection kit, i.e., the purported reasons for which col. 16, lines 53-60 of Wojcik is cited. These allegations are completely erroneous and lack any evidentiary support.

Col. 16, lines 53-60 of WOJCIK states:

FIG. 25 shows the logic tree for the production and receiving

function as implemented in this system and tracks through the product being received from production, palletized, inspected and then delivered to the warehouse where the product is put away and this product is entered into inventory or quarantine with a data base created on location by SKU number, lot, quantity and reason for hold, if it is in quarantine.

However, this cited passage is completely silent with regard to the purported reasons for which it was cited, namely, to cure the critical failures of disclosure or teaching of FLETCHER-HAYNES of the elements claimed herein, including (1) a system for preventing the use of quarantined blood component collection kits, (2) a system computer which has blood component collection kit quarantine information in a database, (3) a system computer which processes the quarantine information in the database prior to use of a blood component collection kit, and/or (4) an interface having a quarantine field for indicating that at least a portion of the blood component collection kit inventory is quarantined.

Indeed, applicants' undersigned counsel also conducted a word search on WOJCIK for the expressions "blood", and "blood component collection kit". None of those expressions are found anywhere in WOJCIK.

While WOJCIK uses the word "quarantine" at col. 16, lines 53-60, it is for a completely different purpose and in a completely different type of system. It is stated at p. 4 of the Office Action that "A reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole [MPEP 2141.01]."

First, the word "quarantine" is briefly mentioned in a single sentence in WOJCIK for use in a completely different system, without any discussion of the purpose or effects of the quarantine. For example, the quarantining in WOJCIK is not (1) in a system for preventing the use of quarantined blood component collection kits, (2) in a system computer which has blood component collection kit quarantine information in a database, (3) in a system computer which processes the quarantine information in the database prior to use of a blood component collection kit, and/or (4) an interface having a quarantine field for indicating that at least a portion of the blood component collection kit inventory is quarantined; all as claimed herein.

Second, contrary to MPEP 2141.01 the matter with which WOJCIK deals, with its commercial ordering and fulfillment system, is completely different than both FLETCHER-HAYNES and the present invention. It is respectfully submitted that no one skilled in the art would combine FLETCHER-HAYNES and WOJCIK, and there is no evidence to the contrary. The burden of proof is on the examiner, and no such evidence has been presented.

Furthermore, it is respectfully submitted that the combination of FLETCHER-HAYNES and WOJCIK is an attempt at a hind-sight reconstruction of the invention claimed herein, which is not permitted.

In conclusion, neither FLETCHER-HAYNES alone, or as modified by the disclosure of the newly cited WOJCIK, results in a system (claims 8-30), a computer readable medium (claims 31-42) or a method (claims 43-54) which include:

- Quarantining unsuitable blood component collection kits,
- Managing the inventory of unsuitable blood component collection kits,
- Providing a database to keep track of the inventory of unsuitable blood component collection kits,
- Preventing the use of unsuitable blood component collection kits, and/or
- Providing an interface with a quarantine field for indicating that a portion of the blood component collection kits is currently in quarantine.

For the above reasons, it is respectfully submitted that Claims 8-54 are in condition for allowance. Accordingly, favorable reconsideration and allowance are requested.

Numerous rejections were also made to the dependent claims. Applicants believe that these claims are allowable for at least the reasons expressed above, and since these dependent claims add additional elements to their respective independent claims. As noted above, independent Claims 8, 31 and 43 should be in condition for allowance. However, applicants reserve the right to more fully address the rejections of the dependent claims at a later time.

CONCLUSION


For the foregoing reasons, it is believed that Claims 8-28 and 30-54 patentably distinguish over the prior art and that these claims are in condition for allowance. Early allowance is respectfully solicited.

A petition for a two-month time extension is enclosed herewith to make the filing of this amendment and the filing of the RCE timely. Payment of the applicable fees is authorized in these documents.

It is not believed that any other fees are due. However, if any additional fees are applicable, kindly charge such fees to our deposit account number 50-1039.

The Examiner is invited to call the undersigned to further discuss any of these matters.

Respectfully submitted,


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